K140214
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FEB 19 2014

TOTOKU

510(k) SUMMARY

Submitted Information:	JVC KENWOOD CORPORATION 3-12, MORIYA-CHO, KANAGAWA-KU, YOKOHAMA-SHI, KANAGAWA, 221-0022 JAPAN
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Date Prepared:	January 20, 2014
Device Name:	6M 30.0 inch Color LCD Monitor CCL650i2 (CL30650, MD302C6)
Common Name:	CCL650i2, CL30650, MD302C6
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Picture Archiving and Communication System)
Predicate Device:	21.3 inch (54 cm) Color LCD Monitor CCL358i2 (CL21358) (K133185)
Device Description:	CCL650i2 (CL30650, MD302C6) is a 6M 30.0-inch Color LCD monitor whose display resolution is 3280 x 2048 supporting DVI (digital visual interface) and DisplayPort.
Intended Use:	6M pixel 30.0 inch Color LCD Monitor, CCL650i2 (CL30650, MD302C6) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is not meant to be used for digital mammography.
Substantial Equivalence:	CCL650i2 (CL30650, MD302C6) realizes 2 (two) 3M screens of the predicate device CCL358i2 (CL21358) (K133185) in one device. The characteristics of CCL650i2 (CL30650, MD302C6) achieves more than that of 2 (two) 3M monitors, CL358i2 (CL21258) (K133185). The both devices do not share common components.

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Technical Specification

1. Luminance uniformity:
   [SPEC] Less than 30% based on AAPM-TG18 4.4. Refer to actual Luminance uniformity data
2. Pixel Defects / Fault
   [SPEC] Class II or more. ISO13406-2
3. Artifacts
   - pixel defects/faults (ISO13406-2):
   - artifacts: miscellaneous including ringing, ghosting, image sticking
4. Chromaticity Measurement of 5%, 50%, 95% Level
   [SPEC] Refer to actual data.
5. Chromaticity
   [SPEC] Delta (u', v') $\leqq$ 0.01 measured at 80% Lmax based on AAPM-TG18 4.8.4
   Refer to actual chromaticity data.

Substantial Equivalence Comparison

	CCL358i2 (CL21358)	CCL650i2 (CL30650, MD302C6)
510(k) Number	K133185	Unknown
Display Area	Horizontal: 433.152mm, Vertical: 324.864mm	Horizontal: 645.504mm, Vertical: 403.0464mm
Input Signal	DVI-D Digital Video Signal, DisplayPort	DVI-D Digital Video Signal, DisplayPort
Maximum Display	1536 x 2048 dots	3280 x 2048 dots
Pixel Pitch	0.2115 x 0.2115mm	0.197 x 0.197mm
Scanning Frequency	DVI 46.6KHz, Vertical: 30Hz (Landscape) 61.9KHz, Vertical: 30Hz (Portrait) 93.1KHz, Vertical: 60Hz (Landscape) 123.9KHz, Vertical: 60Hz (Portrait) DisplayPort 47.4KHz, Vertical: 30Hz (Landscape) 63.2KHz, Vertical: 30Hz (Portrait) 94.8KHz, Vertical: 60Hz (Landscape) 126.3KHz, Vertical: 60Hz (Portrait)	DVI/DisplayPort 126.5KHz, Vertical: 60Hz (3M) *1 123.8KHz, Vertical: 60Hz (3M PLUS) *2 63.2KHz, Vertical: 30Hz (6M) *3 61.9KHz, Vertical: 30Hz (6M PLUS) *4 *1 3M=1536 x 2048 *2 3M PLUS=1640 x 2048 *3 6M=3072 x 2048 *4 6M PLUS=3280 x 2048
Maximum Luminance	410 cd/m^2 DICOM calibrated 800 cd/m^2 typ.as LCD component	410 cd/m^2 DICOM calibrated 800 cd/m^2 typ.as LCD component
Luminance Calibration (Optional)	Software: Medivisor Nx Calibration Sensor: Chroma5 (X-Rite)	Software: Medivisor Nx Calibration Sensor: Chroma5 (X-Rite)
Contrast Ratio	1400:1	1000:1
Serial Communication	USB: upstream port (x 1), downstream port (x 2)	USB: upstream port (x 1), downstream port (x 2)
Safety Standards	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No.60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B)	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No.60601-1, FCC (Class B), MDD/CE, VCCI-B (Class B)
Weight & Dimension	Net: 12kg 474(w) x 468.4 - 529.9(H) x 220(D) mm (Landscape) 367(w) x 521.9 - 583.4(H) x 220(D) mm (Portrait) Packed: 15.0kg 470(w) x 670(H) x 340(D) mm	Net: 15.5kg 695.6(w) x 512.1 – 573.6(H) x 243.5(D) mm Packed: 20.3kg 791(w) x 690(H) x 344(D) mm
Power Supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz

CCL650i2 (CL30650, MD302C6) can be considered to have equivalent display performances to those of the predicate device CCL358i2 (CL21358) (K133185) due to the following reasons:

a. The maximum display size (3280 x 2048) is twice or more larger than that of the predicate device (1536 x 2048) and the active area size (645.504mm (H) x 403.0464mm (V)) is larger than that of the predicate device (433.152mm (H) x 324.864mm (V)). The proposed 6M device realizes two 3M screens in one device.

b. The DICOM calibrated luminance values of the both devices are the same (410 cd/m^2 and the typical maximum luminance values are also same (800 cd/m^2) between the both devices. The high luminance to be maintained constantly was realized by the employment of LED backlight deteriorating more slowly than conventional CCFL backlights.

c. The LED backlight is employed with both CCL650i2 (CL30650, MD302C6) and the predicate device CCL358i2 (CL21358) (K133185) because it is mercury-free, consumes less power and deteriorates slowly. We have not recognized any adverse effects of the LED backlight on the quality of displayed images. Refer to "Technical Data" where several image quality characteristics of the proposed device are compared with those of the predicate device.

d. The both devices display images in accordance with DICOM GSDF by default utilizing the factory calibrated display mode stored in lookup tables inside of them.

e. Both devices support Digital Visual Interface (DVI) and DisplayPort.

f. Pixel pitch of CCL650i2 (CL30650, MD302C6) 0.197mm x 0.197mm is smaller than that of the predicate device CCL358i2 (CL21358) (K133185) 0.2115mm x 0.2115mm. The proposed device can display image more finely than the predicate device.

g. CCL650i2 (CL30650, MD302C6) can display in 6 modes:
   1) Full DVI (6M) 3280 x 2048 (30Hz)
   2) Input 1: DVI (3M) 1640 x 2048 (60Hz), Input 2: DVI (3M) 1640 x 2048 (60Hz)
   3) Input 1: DVI (3M) 1640 x 2048 (60Hz), Input 2: DP (3M) 1640 x 2048 (60Hz)
   4) Input 1: DP (3M) 1640 x 2048 (60Hz), Input 2: DVI (3M) 1640 x 2048 (60Hz)
   5) Input 1: DP (3M) 1640 x 2048 (60Hz), Input 2: DP (3M) 1640 x 2048 (60Hz)
   6) Full DP (6M) 3280 x 2048 (30Hz)
   This unique characteristics is only for the proposed device.

As for the maintenance, the same QC software is used for both devices. Both devices have Front Sensor to stabilize the luminance.

As for built-in sensors, both devices have 2 (two) kinds of common sensors, Front Sensor and Ambient Light Sensor. Front Sensor is related to the maintenance or calibration and Ambient Light Sensor is used to measure the ambient light by lx. Front sensor enables automatic grayscale calibration by measuring the luminance at the screen surface. Without Front sensor, the grayscale calibration process requires human intervention and the use of and external sensor. The accuracy data of the calibration with external sensors and that with Front Sensor is included in section 9 "Verification & Validation" in "Application".

The overall design of the CCL650i2 (CL30650, MD302C6) has been validated in accordance with internationally recognized Safety and EMC standards by third-party certifiers. Besides, JVC KENWOOD Corporation performed a range of system and performance tests to ensure that the CCL650i2 (CL30650, MD302C6) performs in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance.

Conclusion

The 6M pixel Color LCD Monitor, CCL650i2 (CL30650, MD302C6) is substantially equivalent to 2 (two) of the predicate 3M device with respect to technical characteristics, application and intended use. The specifications of the primary component employed by the proposed device are not the same to those of the predicate device, but the proposed device has been accepted by the same Safety Standards of the predicate device and the differences have been independently validated. Any differences between the devices do not affect safety or effectiveness. Therefore, the proposed device CCL650i2 (CL30650, MD302C6) were determined to be substantially equivalent to the predicate device CCL358i2 (CL21358) (K133185).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 19, 2014

JVC KENWOOD Corporation
% Mr. Tsukasa Tashiro
General Manager
3-12, Moriya-Cho, Kanagawa-Ku
Yokohama-Shi, Kanagawa 221-0022
JAPAN

Re: K140214
Trade/Device Name: 6M 30.0 inch Color LCD Monitor CCL650i2 (CL30650, MD302C6)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 21, 2014
Received: January 28, 2014

Dear Mr. Tashiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
Not known K140214

Device Name
CCL650i2 (CL30650, MD302C6)

Indications for Use *(Describe)*
6M pixel 30.0 inch Color LCD Monitor CCL650i2 (CL30650, MD302C6) is intended to be used in displaying and viewing medical images for diagnosis by trained Medical practitioners. It is not meant to be used in digital mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*